

document in the **Federal Register** establishing a new effective date.

II. Administrative Procedure Act

Notice and comment is not required when an agency delays the effective date of a rule under section 705 of the APA because such a stay is not substantive rulemaking; it merely maintains the status quo to allow for judicial review.³

To the extent that a delay in the effective date may be deemed a rule, such action is also exempt from notice and comment as a rule of procedure under 5 U.S.C. 553(b)(A).⁴ Alternatively, the Commission finds, for good cause, for the reasons stated above, that notice and solicitation of public comment regarding the delay of the effective date for the CARS Rule are impracticable, unnecessary, or contrary to the public interest pursuant to 5 U.S.C. 553(b)(B). Balancing the equities here, the Commission has determined that it is in the interests of justice to stay the effective date of the Rule to allow for judicial review.

By direction of the Commission.

April J. Tabor,
Secretary.

[FR Doc. 2024–03559 Filed 2–21–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2024–N–0017]

Advisory Committee; Digital Health Advisory Committee; Addition to List of Standing Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the standing advisory committees regulations to add the establishment of the Digital Health Advisory Committee (the Committee) to the list of standing advisory committees.

DATES: This rule is effective February 22, 2024.

³ See *Bauer v. DeVos*, 325 F. Supp.3d 74, 106–07 (D.D.C. 2018); *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 28 (D.D.C. 2012).

⁴ Because a notice of proposed rulemaking is not necessary for this delay of effective date, the Commission is not required to prepare a regulatory flexibility analysis under the Regulatory Flexibility Act. See 5 U.S.C. 603(a), 604(a).

FOR FURTHER INFORMATION CONTACT:

James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993, 301–796–6313, James.swink@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Committee was established on October 11, 2023, and notice of establishment was published in the **Federal Register** on October 12, 2023 (88 FR 70679).

The Committee will provide advice to the Commissioner, or designee, on complex scientific and technical issues related to digital health technologies (DHTs). This also may include advice on the regulation of DHTs and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee will advise the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee will provide relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee will perform its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of digital health, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in

clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as special government employees or non-voting representatives. Federal members will serve as regular government employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with and represent industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Committee name and function have been established with the establishment of the Committee charter. The change became effective October 11, 2023. Therefore, the Agency is amending § 14.100 (21 CFR 14.100) to add the Committee name and function to its current list as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely amends § 14.100 to include the name of the committee and its function that will be added consistent with the committee charter.

Therefore, the Agency is amending § 14.100 as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

- 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. 1001 *et seq.*; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264, 284m, 284m–1; Pub. L. 107–109, 115 Stat. 1419.

■ 2. In § 14.100, add paragraph (d)(6) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(6) Digital Health Advisory Committee.

(i) Date established: October 11, 2023.

(ii) Function: Advises the Commissioner of Food and Drugs or designee in discharging responsibilities as they relate to ensuring that digital health technologies (DHTs) intended for use as a stand-alone medical product, as part of a medical product, or as a companion, complement, or adjunct to a medical product are safe and effective for human use.

* * * * *

Dated: February 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03618 Filed 2–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 525

Publication of Burma Sanctions Regulations Web General License 6

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Burma Sanctions Regulations: GL 6, which was previously made available on OFAC's website.

DATES: GL 6 was issued on January 31, 2024.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: <https://ofac.treasury.gov>.

Background

On January 31, 2024, OFAC issued GL 6 to authorize certain transactions otherwise prohibited by the Burma Sanctions Regulations, 31 CFR part 525. GL 6 was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. The reference to 31 CFR part 594 in paragraph (a) of the GL rather than 31 CFR part 525 was an error in the original GL, which is reproduced in this publication. The text of the GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Burma Sanctions Regulations

31 CFR Part 525

GENERAL LICENSE NO. 6

Authorizing the Wind Down of Transactions Involving Shwe Byain Phyu Group of Companies

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the Burma Sanctions Regulations, 31 CFR part 594 (BuSR), that are ordinarily incident and necessary to the wind down of any transaction involving Shwe Byain Phyu Group of Companies (SBPG) or any entity in which SBPG owns, directly or indirectly, a 50 percent or greater interest, are authorized through 12:01 a.m. eastern standard time, March 1, 2024, provided that any payment to a blocked person is made into a blocked account in accordance with the BuSR.

(b) This general license does not authorize any transactions otherwise prohibited by the BuSR, including transactions involving any person blocked pursuant to the BuSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: January 31, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–03625 Filed 2–21–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General License 87

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 87, which was previously made available on OFAC's website.

DATES: GL 87 was issued on February 8, 2024. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT:

OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: <https://ofac.treasury.gov>.

Background

On February 8, 2024, OFAC issued GL 87 to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. GL 87 was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 87

Authorizing Limited Safety and Environmental Transactions Involving Certain Persons or Vessels Blocked on February 8, 2024

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 that are ordinarily incident and necessary to one of the following activities involving the blocked persons described in paragraph (b) are authorized through 12:01 a.m. eastern daylight time, May 8, 2024, provided that any payment to a blocked person must be made into a blocked account in accordance with the Russian Harmful Foreign Activities Sanctions Regulations (RuHSR):

(1) The safe docking and anchoring in port of any vessels in which any person or entity listed in paragraph (b) of this